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A Novel Soft Robotic Supernumerary Hand for Severely Affected Stroke Patients

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***Abstract*—Upper limb functions are severely affected in 23% of the chronic stroke patients, compromising their life quality. To re-enable hand use, providing a degree of functionality and motivating against learned non-use, we propose a robotic supernumerary limb, the *SoftHand X* (SHX), consisting of a robotic hand, a gravity support system, and different sensors to detect the patient's intent for controlling the robotic hand. In this paper, this novel compensational approach is introduced and experimentally evaluated in stroke patients, assessing its efficacy, usability and safety. Ten patients were asked to perform tasks of a modified Action Research Arm Test with the SHX, by using three input methods. The mARAT scores rated the potentiality of the system. Usability was evaluated with the System Usability Scale, while spasticity before and after use was measured by the modified Ashworth Scale (mAS). Nine patients, not able to perform any tasks without external support, completed the whole experimental procedure using the proposed system with a median score greater than 12/30. Among the three input methods tested, the usability of one was rated as "good" while the other two were rated as "ok". Seven patients exhibited a reduction of the mAS. All nine patients stated that they would use the system frequently. Results obtained suggest that the SHX has the potential to partially compensate severely impaired hand function in stroke patients.**

***Index Terms*—Supernumerary Limbs, Extra-thesis, Upper Limb, Stroke, Soft Robotic.**

I. Introduction

STROKE is one of the leading causes of disability worldwide [1]. Eighty percent of the stroke patients experience motor deficits of the upper limb early after stroke [2], and about 23% of them have persisting upper limb impairment [3]. These motor deficits particularly hamper stroke subjects in performing Activities of Daily Living (ADL; e.g. eating, preparing meal, or carrying objects), which in the majority of the cases require using both hands [4]. The impact of these deficits go even further and have shown to negatively correlate with the patients' quality of life [5].

(a) (b)

Fig. 1. In (a) the whole system is shown. Fig. (b) shows a stroke patient performing a grasping task with the supernumerary robotic system. The figure shows the sub-parts constituting the overall architecture of the system: (1) the SoftHand X, (2) the gravity compensation system, (3) the human-arm interface, and (4) the bending sensor as one of the possible input interfaces.

Stroke recovery mainly takes place within the first months after symptom onset [6]. However, severely affected stroke patients have very limited chances to regain complete function e.g. in patients who have no voluntary shoulder abduction and finger extension early after stroke and in which the corticospinal tract is disrupted [7], [8]. Until date, there is no effective rehabilitation intervention that restitutes function in these severely affected patients [9], [10]. It may also happens that, the patient partially recovers his/her upper limb functionality, but not totally. In this case, one of the risks is related about the *learned non-use* phenomenon [11], i.e. the tendency to not use the paretic limb [11]. The limited functionality of the affected limb leads the patient to use it less and less, generating a suppression of those behaviors that could involve the limb. As a result, the patient never learns that the limb itself may have become potentially useful again [11], and the lack of training may lead to the progressive deterioration of motor function [12]. To counter learned non-use, Constraint-Induced Movement Therapy (CIMT) is effective, but this form of therapy is only suitable for patients who have mild motor impairments of the upper limb [13]. Alternative therapies have been proposed using e.g. Virtual Reality reinforcement [12]. Nevertheless, to enhance the patients ability to integrate the affected arm in daily life activities, alternative solutions have to be developed, e.g. robotic-enabled assistance. Although the real advantages of robotic solutions are still questioned [14], numerous prototypes have been developed in the last two

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decades [15], some of which show comparable results to standard therapies [16]. Several of these devices, specifically designed to rehabilitate functions, are not equally convenient for chronic stroke subjects with severe upper limb paresis, for whom further recovery is unlikely [3]. In such cases, a *compensatory* approach is often preferred [17]. Robotic devices might be useful to compensate movements of the severely affected upper limb, which otherwise remains unused. This is evident in some daily life actions where patients try to accomplish tasks using only one hand, or substituting the use of the impaired hand with other parts of their body (e.g. their mouth to tear a package open). Taking into account that most of the ADLs require bi-manual ability [18], single-(unaffected) arm compensatory techniques are of limited help in daily life. For this reason, robotics compensatory devices could be particularly advantageous in patients with severe impairments for support in ADLs [10]. As an example, the Hankamp Rehab Mobile Arm Support (HR-MAS)[1], a passive gravity compensator arm support was designed to reduce the gravity effect on the user's arm, compensating the reduced mobility of the proximal part of the upper limb. The HR-MAS has already been used in clinical studies, which demonstrated its beneficial support to patients [19]. Unfortunately, arm-support devices fall short of providing compensation for one of the most important functions of the upper limb, i.e. grasping and manipulation of objects. If patients could be assisted with some of the functionalities of their impaired hands, their quality of life, as well as their motivation to keep using and exercising their remaining upper limb functions, would be greatly improved.

A non-invasive approach in this direction is the use of Supernumerary Robotic Limbs (SRL). SRLs have been initially proposed for industrial purposes, to improve the user's ergonomics and enhance his/her capabilities [20], [21]. Typical SRL consist of additional robotic body parts (e.g. limbs and/or fingers), which augment the user's abilities. Differently from exoskeletons [15], they do not request for any joint-to-joint alignment. Moreover, they not force the user to follow a specific trajectory with his/her own body parts. In the last few years, concept of SRL was further explored for clinical use and led to the development of a first SRL for post-stroke patient assistance in grasping [22]. The device name, "Sixth Finger", aptly describes its function: it consists of an additional finger, which acts as an extra thumb, and opposes the parethic hand allowing to grasp objects in between. To the best of our knowledge, this is the first and so far only SRL system designed and tested for clinical purposes in stroke patients.

Supernumerary artificial hands have been used, with different goals, by Aszmann and colleagues for patients with a brachial plexus injury [23]. In this study, three patients voluntarily enrolled for a bionic reconstruction of their hand. For this purpose, patients used a supernumerary artificial hand (before the elective amputation) to figure out the efficacy of such hand with respect their affected hand.

In this study we propose and explore the use of a supernumerary robotic hand for compensating upper limb movements in chronic stroke patients. The leading hypothesis is that the proposed system should enhance the residual patients' arm functionality enough for motivating him/her to actively contribute to the task execution. In fact, the system does not substitute the patient's arm functionality, but it just *compensate* the missing abilities. In this way, the patient is pushed to use as much as possible his/her residual capabilities, in coordination with the device to accomplish daily life tasks.

II. Material

The supernumerary system presented in this work, shown in Figure 1, is composed by five functional sub-parts: (1) a robotic hand, the SoftHand X; (2) a passive gravity compensator, the Hankamp Rehab Mobile Arm Support (HR-MAS); (3) a human-arm interface, that enables the connection between sub-parts (1) and (2), permits the natural (residual) movements of the patient's forearm, and allows the integration of a mechanism for the pro-supination movement of the robotic hand; (4) the input interfaces used by the patient to control the robotic hand; (5) and a remote workstation used to control and monitor the system. The software and electronic framework behind the system architecture is derived from the open source platform Natural Machine Motion Initiative [24][2].

A. Robotic hand

The SoftHand X (SoftHand eXtrathesis) is a derivation of the robotic hand prosthesis SoftHand Pro [25]. It has 19 degrees of freedom and an anthropomorphic structure. The actuation architecture is based on an under-actuated system, which implements the synergistic behavior of the human hand [26]. Three main features make this artificial hand interesting for the use as SRL: i) the self-adaptive grasp behavior (enabled by the synergistic actuation layout), which makes the hand capable to grasp and manipulate objects (of different shapes and sizes) in several different functional ways [27]; ii) the lower dimensionality actuation architecture, which enables the use of simple and intuitive control approaches (discussed in Section II-D); and iii) the specific joint design of the phalanges, based on soft robotic technologies, which makes the hands' fingers resistant to dislocations and bumps. Indeed, given the presence of only one actuation unit, just few input signals are needed. Overall dimensions of the SoftHand X are: 20 cm (palm + middle finger length), 10 cm (palm width) and 5 cm (palm thickness). Maximum grasping forces are: 80 N power grasp (cylindrical object, diameter 80 mm), 30 N pinch grasp (flat object, height 2 mm). Weight: around 500 g. The SoftHand X is powered by a Maxon Motor DCX22S equipped with a GPX22 planetary gearbox. An Austrian Microsystem magnetic encoder is used to read the position of the motor and close the control loop. A custom electronic board [24] is used to drive the hand and interface with the input devices described in Section II-D. In particular, a PID controller is implemented on it for commanding the reference position starting from the sensor signal [24]. Parameters of the controller was tuned with the Ziegler-Nichols method.

[1]Distributed by Hankamp Rehab, 7544 RG Enschede, Nederland.

[2]NMMI web-site platform: www.naturalmachinemotioninitiative.com

B. Gravity compensator

The HR-MAS is a passive gravity compensator, used in this study to support the mass of the SoftHand X, the patient's upper limb and the mechanical interface for the arm support. This kind of assistance is essential because of the severe impairment level of the patients that we target with our SRL system. The presence of the gravity compensation system can, in turn, extend the active range of motion of the patient's upper limb [28], and potentially reduce muscular fatigue, augmenting the activity time and improving the arm force control.

C. Human-arm interface

The gravity compensator and the robotic hand are integrated by a customized human-arm interface (shown in Figure 2(a)). The mechanical design of this interface was driven by the need of optimally placing the robotic hand, ensuring a high comfort in supporting the patient's arm. To do this, a first prototype was studied and tested in [29]. Then, it was adapted and upgraded taking in consideration feedback from clinicians and pilot tests with patients. In this new version, the patient's arm can be attached to the human-arm interface through the convenient use of armbands composed of foam pads and Velcro straps. The natural (residual) movements of the patient's forearm, shown in Figure 3(a), are guaranteed by the kinematic mechanisms highlighted in Figure 2(b). The pronation/supination movement of the robotic hand is implemented thanks to the presence of a passive wrist (3 in Figure 2(a)) positioned between the robotic hand and the human-arm interface. It gives the possibility of a 360° rotation, and allows the user a more convenient pre-grasp configuration, as depicted in Figure 3(b). In this way, the patient can set the proper angle anytime he/she wants, accordingly with his/her needs and preferences. To minimize the gravity torques, and reduce annoying rotations of the human arm, the mass of the robotic hand is balanced through a system of counterweight. An aluminum alloy bracket (shown in Figure 2(b)) is specifically designed and integrated with a sliding mass/counter-mass system, composed by two sliding aluminum alloy beams (Figure 2(c)) and an elbow stop (n.2 in Figure 2(a)). The mass that must be balanced corresponds to the mass of the SoftHand X, while the counter-mass is a cylinder of $800g$ fixed on the elbow stop. The designed human-arm interface allows three different adjustments, as shown in Figures 2(d) and 2(e)): translation of the mass along the arm direction (forward/backward), translation of the counter-mass along the arm direction (forward/backward), and translation of the whole arm support on the horizontal plane (right/left). In addition, the relative vertical translations of the mass with respect to the counter-mass permits to match correctly the proper patient's arm length. An ergonomic handle (4 in Figure 2(a)), with a strap, is attached to one of the sliding beams and positioned on top of the robotic hand. The handle is designed in order to allow a stable connection between the human-arm interface and the patient's natural hand. Moreover, this handle can be opportunely substituted and/or adapted with one of the input interfaces, minimizing its impact on the patient's fingers/hand movement.

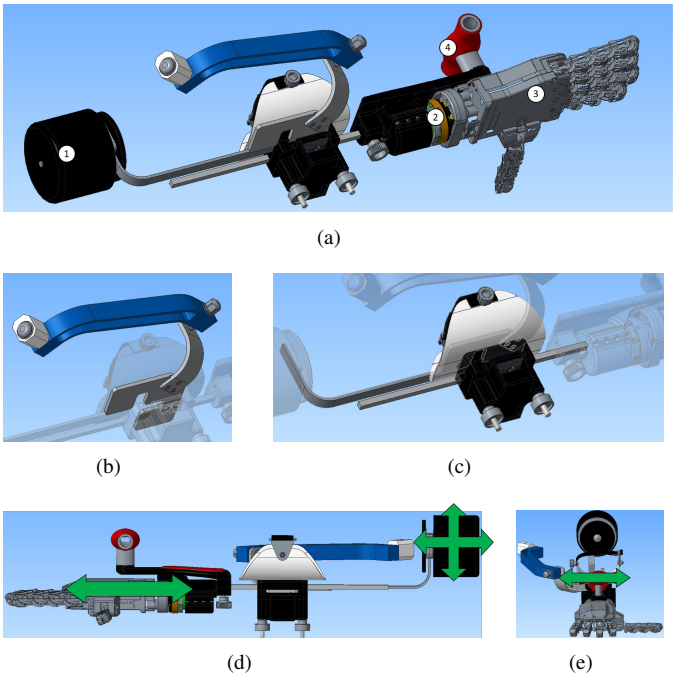

Fig. 2. In (a), a bottom-lateral view of the custom human-arm interface is reported. The elbow stop, the passive wrist, the SoftHand X and the ergonomic handle are labeled respectively with number 1, 2, 3 and 4. In (b), it is shown the aluminum bracket, which allows the natural (residual) movements of the patient's forearm. In (c), it is reported the support where the patient's arm is positioned on the human-arm interface and the architecture of the mass/counter-mass system composed by two sliding beams. The sliding movements are shown in (d) and (e), highlighted by green arrows.

D. Input Interface

In order to control the opening and closing of the SoftHand X, the system has been equipped with three customizable input interfaces, based on three different sensing technologies:

1) Grasp force handle: in this input method, a measure of the residual grasp strength of the patient's affected hand is provided by a couple of force sensors (Micro Load Cell, Phydgets), integrated in a handle that can be mounted on the human-arm interface. The handle is composed by a cylindrical structure (3D printed in ABS), which embeds the force sensors and their electronics, as shown in Figure 4(a). The cylinder is connected to an aluminum alloy bar through two laterals clamps (see Figure 4(a)). The grasping force is a measure of the grasping action applied on the bar by the patient's fingers (see Figure 4(a) and Figure 4(c)). The presence of the two force sensors on the extreme sides of the cylinder permitted to estimate the grasping force even if the patient hand was not centrally positioned on the handle. The force signal is amplified (instrumentation amplifier AD620, Analog Devices) and carried to the analogical port of the electronic board into the workstation (see Sec. II-E)

2) Bending sensor: this input method is based on the measurement of the flexion/extension of the patient's fingers by a bending sensor (resistive flex sensor, Spectra Symbol) placed into a finger glove made of elastic tissue (Figure 4(e)), at the metacarpophalangeal joint level of the middle finger. Although just one finger is recorded, a full hand closure is asked to the patient. In this way, the synergistic behavior of the robotic hand makes it to appear as replicating the real hand

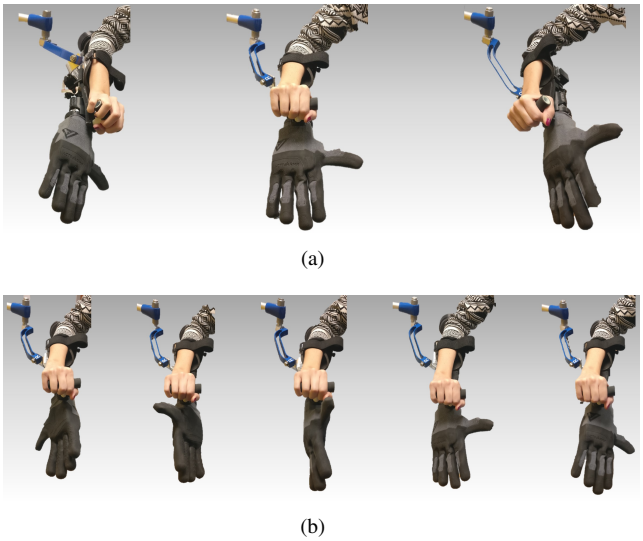

Fig. 3. In the picture, the pro-supination allowed by the system is shown. Sequence (a) shows the natural (residual) movements of the patient's forearm allowed by the human-arm architecture. Sequence (b) shows five possible positions of the SoftHand X, permitted by the passive wrist, which allows for a 360° rotation of the robotic hand.

movement, making its control more intuitive . The bending sensors can be placed on both the non-affected and affected hand, on any finger of the hand. In this study it was used on the unaffected side. The bending signal is delivered to the analogical port of the workstation electronic board (see Sec.II-E) through a specific calibration circuit, as suggested by its data-sheet.

3) Trigger: in this case, inputs come from a lever (Figure 4(b)) fixed to a floating knob, separated from the SHX and its support. The patient thus controls the SHX with his/her unaffected hand (see Figure 4(g)). An electromagnetic encoder (AS5045, Austrian Microsystem) measures the rotation angle of the lever, as shown in Figure 4(b). The angle value is provided to the digital port of the electronic workstation board (see Sec. II-E) through the SSI communication protocol.

As shown in Figures 4(d), 4(f) and 4(h), a proportional control strategy has been implemented for controlling the SoftHand X, to follow inputs independently from the type. It means that the robotic hand opens (or closes) proportionally to the magnitude of a measured signal (please note that the low-level controller of the hand motor is always the same). The proportionality is estimated through a calibration procedure, measuring the maximum and the minimum reachable signal by the patient. This kind of control can be used in two different modalities, voluntarily open and voluntarily close [30]. In the voluntarily open mode, the increase of the signal makes the robotic hand close (the rest position corresponds to an open robotic hand). In the voluntarily close mode the signal increase opens the robotic hand (the robotic hand is closed at rest).

E. Workstation

The input interfaces and the SoftHand X are connected to a remote battery pack, integrated with an electronic board [24], based on Cypress Programmable System on Chip-PSoC, with RS485 communication protocol. The pack is connected to a remote workstation trough an USB cable. The clinician

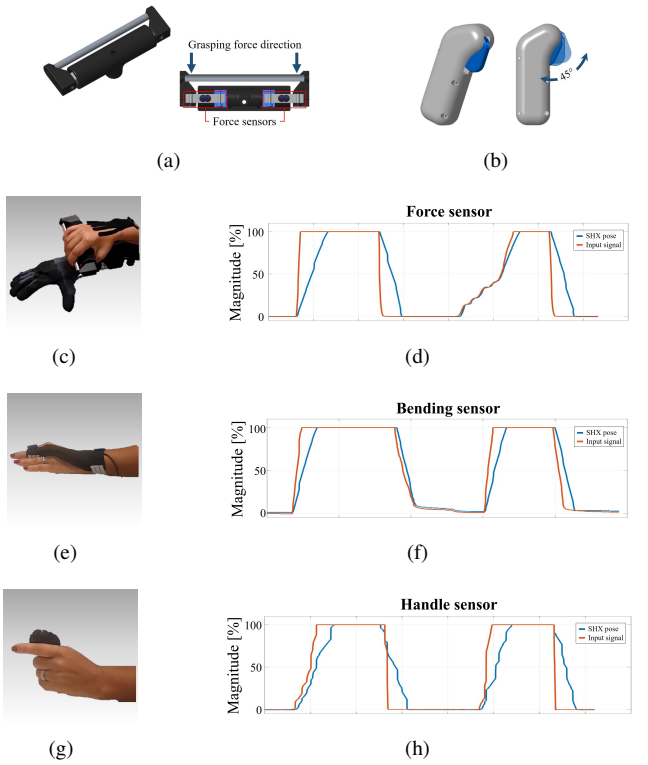

Fig. 4. In (a) it is shown the CAD representation of the grasp force handle, in (b) of the trigger (together with the movements of the lever around its pin). In (c), (g) and (d) the prototype of the grasp force handle, the bending sensor and the trigger are shown respectively. In (d), (f) and (h) the signals of two consecutive closures of the SoftHand X are plotted. In particular, the real motor pose of the SoftHand X (blue line) and the input signal (red signal) are shown for the three input interfaces.

can monitor and setup the used input interface through a Matlab/Simulink (v. 2018a) Graphical User Interface (GUI) implemented on the remote PC. The GUI allows the clinician to save patient's data, to setup the proper calibration configuration, and to start/pause/stop the system.

III. Methods

Ten chronic stroke patients (characteristics reported in Table I) were involved in a single-session study conducted in July and August 2018, at the University Hospital Zurich (Zurich, Switzerland) and at the "Zürcher RehaZentren Klinik Wald" (Wald, Switzerland). To be included in the study, patients had to have a unilateral ischemic or hemorrhagic chronic stroke and severe residual hemiparesis of the upper limb. The patients had minimal or no voluntary ability to flex/extend the fingers of the paretic side, i.e. score below 2 for both the finger extension and flexion item of the Upper Extremity sub-scale of the Fugl-Meyer Assessment

(Fugl-Meyer Assessment - Upper Extremity Finger extension and flexion sub-score below 2). Additional exclusion criteria were as follows: major comprehension or memory deficits, severe neglect and pain syndrome on the disabled upper extremity. All participants gave written informed consent in accordance with the declaration of Helsinki. The cantonal ethics in Zurich approved the experimental protocol prior to start of the study (Req-2017-00972).

The workflow of the experimental protocol (presented in details in Section III-A) was as follows: first, the supernumerary system was introduced to the patient, highlighting the main features. Then, the patient's demographic and clinical data were recorded by the therapist, who then inquired the patient's familiarity with technology and assistive devices. Next, the patient was instructed to don the supernumerary hand and the therapist set properly the balancing adjustment. Here, the comfort of the system was inspected by a questionnaire. After that, the patient performed the experimental tasks of a modified version of the Action Research Arm Test (mARAT), which consisted of manipulating and picking and placing objects using the presented system. The whole test was repeated three times, one for each input interface. After having tested each input, the usability was assessed through the System Usability Scale (SUS) questionnaire. After finishing the three repetitions, a clinical evaluation of the patient was conducted for observing variation of the muscle tone due to the use of this novel system. Finally, the patient's perspective was collected through a last questionnaire. The experimental procedure lasted two hours per patient. None of the patients had experience of the use of the system before.

A. Measurement protocol

The following patients' characteristics were collected: demographics, body measurement (e.g. arm length, hand length), the Upper Extremity sub-scale of the Fugl-Meyer Assessment (FMA-UE, maximum score 66, with higher scores being better) [31], and the modified Rankin Scale (mRS, maximum score 5, with lower scores being better) [32]. The patient's confidence with technology and assistive devices was then investigated by a semi-structured interview. Once the questionnaire was finished, the participant was instructed to place his/her impaired arm on the human-arm interface and to attach it with two straps, one on the forearm and one on the hand. Before starting to move, balancing adjustment and positioning of the human-arm interface and the HR-MAS was required to improve the comfort of the patient (as described in Section II-C). Wearing comfort of the system was then inquired with a structured interview of four questions. Subsequently, the patient was instructed to perform the mARAT (original version presented in [33]) with his/her disabled arm (score range 0-30, with higher scores being better). Herewith, the patient had to grasp and manipulate different objects with the supernumerary hand. Due to the presence of the SoftHand X and the HR-MAS, the classical version of the ARAT test has been modified in order to have the target point at $14\ cm$ above the table top, instead of $37\ cm$. The horizontal starting and target positions for each object were $5\ cm$ and $25\ cm$ from the edge of the table. The tasks were performed in a sitting position at a table (height $70\,cm$), and the objects used were four wooden cubes (10, 2.5, 5 and $7.5\ cm$), a cricket ball ($7.5\ cm$ diameter), a sharpening stone, a drinking glass, two tubes ($2.25 \times 11.5\,cm$ and $1.0 \times 16.0 cm$) and a marble ($1.5 cm$ diameter). Participants were asked to grasp each object with the robotic hand and position them on a marked target area ($14\,cm$ higher). For the drinking glass, the patient had to pour its contents into another similar glass positioned on the table, at the same level. The objects were presented to patients in the order listed above. The task execution was scored by the clinician as follows: 3 points when the participant could grasp the object, lift and position it on the target area in the first attempt; 2 points when the participant could grasp the object, transport and place it needing several attempts; 1 point when the participant could grasp and lift the object but was not able to transport it, and 0 points when the participant was not able to grasp the object. To test all the designed input interfaces, the mARAT was performed three times, apart for participants with no voluntary finger flexion/extension, who could not use the grasp force sensor. The order of the three input interfaces were selected randomly for each participant, to minimize bias. Once the test was finished using one input interface, the patient was asked to fill out the SUS questionnaire [34], which is commonly adopted for assessing the usability level of a novel system. Its questions are scored on a five-point Likert-like scale, ranging from "strongly agree" to "strongly disagree", translated to a range of 0-100, where higher scores indicate better usability. Scores below 50 reveal poor usability, suggesting that the use of the system will be limited due to low compliance. Scores above 71 suggest good usability, above 85 excellent and above 90 best imaginable usability [35]. After the three repetitions, a customized interview with six questions was done. Questions aimed to get the patient's preferences regarding the use of this novel system for therapy and/or in daily life. The modified Ashworth Scale (mAS) [36] was assessed before and after the experimental session to monitor the muscle tone. It gives an estimation of the patient's muscles resistance against passive movement, by ranking it from 0 (no spasticity) to 4 (affected part rigid in flexion or extension). Finally, in order to evaluate the safety for using the system, any adverse events (e.g pain occurrence, system failure) were reported.

TABLE I
DEMOGRAPHIC PATIENTS' DATA

Patient data	**Median (Q1 - Q3)**
Total [n]	10
Female [n]	3
Age [years]	66 (52 - 70)
Months post stroke [n]	36 (22 - 103)
Ischemic stroke [n]	7
Hemorrhagic stroke [n]	3
Dominant side (right) [n]	8
Impaired side (right) [n]	5
modified Rankin Scale	3 (3.00 - 3.75)

Legend: Q1 = first quartile; Q3 = third quartile

IV. RESULTS

All results are presented in terms of three values: median (first quartile – third quartile).

The motor impairment level of the affected upper limb, assessed with the FMA-UE (reported in Table II), among the ten patients was 14 (11-17). The hand items (related to mass extension and flexion) amounted to 1 (1 – 2), confirming the severe impairment status of the patients.

TABLE II
FUGL-MEYER ASSESSMENT - UPPER EXTREMITY (FMA-UE)

Patient ID	FMA-UE					Total (66)
	Refl. (6)	Prox. (30)	Wrist (10)	Hand (14)	Coord. (6)	
1	4	7	1	2	0	14
2	4	6	0	1	0	11
3	4	13	3	2	0	22
4	4	9	1	2	0	16
5	4	8	0	1	0	13
6	4	10	0	2	1	17
7	4	14	2	3	0	23
8	4	10	0	1	0	15
9	4	3	0	0	0	7
10	4	5	0	1	0	10
Median	4	8	0	1	0	14
Q1	4	6	0	1	0	11
Q3	4	10	1	2	0	17

Legend: Refl. = Reflexes; Prox. = Proximal; Coord. = Coordination; Q1 = first quartile; Q3 = third quartile

The mARAT scores and the usability results obtained from the patients are listed in Table III and plotted in Figure 5. Although not numerically reported, none of the patients was able to accomplish the test (null score) without the proposed system. All input interfaces were setup with proportional control in voluntarily open modality (see Section II-D). Only 6 out of 10 patients completed the mARAT test by using the grasp force handle interface. Two patients were excluded because of complete lack of finger flexion/extension, which resulted in no hand grasping force. One patient stopped the experiment due to shoulder pain, and one was not able to start due to a technical issue[3]. The mARAT score for this input interface was 13 (7.5 - 15.5). Regarding the bending sensor input interface, only 7 out of 10 patients completed the experimental tasks. Shoulder pain, physical exhaustion and the technical issue caused the three interrupted experimental protocols. With this input interface, the mARAT score was 12 (9 - 18.5) points. Finally, 9 out of 10 patients used the trigger input interface with a score of 17 (13 - 25) points. The dropout was caused by the technical issue.

The SUS median score of the three different input interfaces resulted in: 75.0 (63.8 - 77.5) for the grasp force handle, 72.5 (51.3 - 75.0) for the bending sensor and 82.5 (70.6 - 86.9) for the trigger sensor. Based on the sub-scale scores, patients found the system complex and cumbersome if used without external assistance. Nevertheless patients found the system easy and used it confidently, if assisted by a clinician.

Results of Questionnaire 1 showed that the majority of patients were used to technologies like smartphone (9 out of 10 patients) and personal computer (8 out of 10 patients), while very few of them were confident with assistive technologies such as car control technology (2 out of 10 patients) and electronic foot drop brace (1 out of 10 patients).

[3]An accidental stretch of a cable damaged the electronic board at the beginning of the session and could not be repaired in time before the patient had to leave.

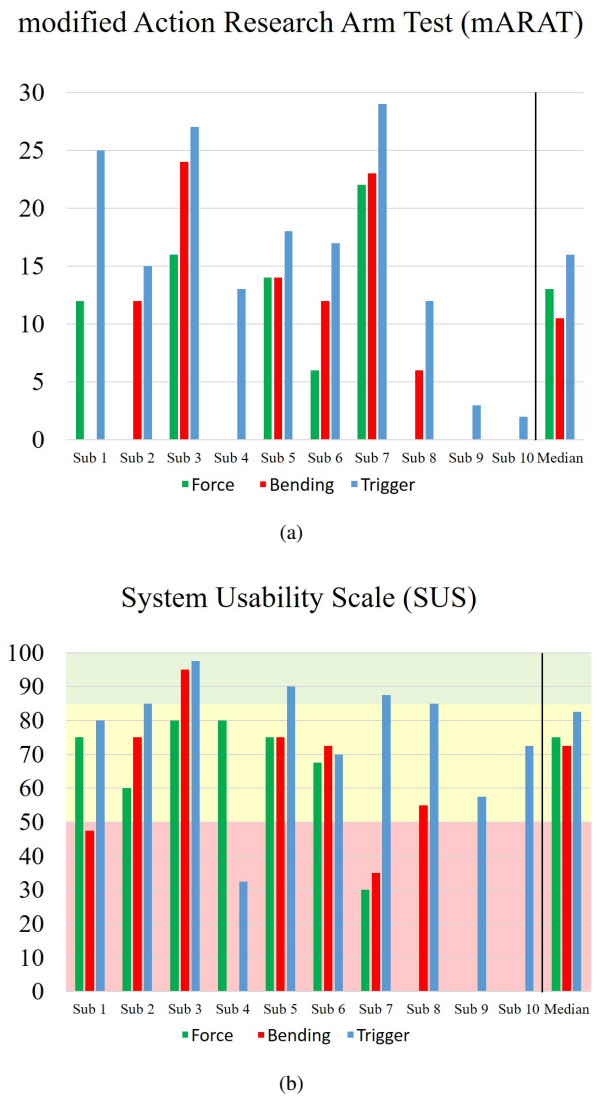

Fig. 5. Graph (a) shows the mARAT performance results of the ten subjects and the median value for each of the input interfaces. Graph (b) shows the usability results of the ten subjects and the median value for each of the input interfaces. Colored background in this graph displays three different score area: light-red for poor usability (SUS score $<$ 50), light-yellow for good usability (SUS score between 50 - 85) and light-green for excellent usability (SUS score $>$ 85).

Results of Questionnaire 2 are within the range 0 (not at all) - 4 (absolutely). The comfort in wearing the device was rated 3 (2.25 - 3), and the feeling of heaviness was rated 1 (0 - 2.5). Regarding the difficulties in fixing the device by using a single hand (i.e. autonomously) and the easiness in adapting it to the arm, the scores were 0.5 (0 - 1) and 3 (2.25 - 3.75) respectively.

For Questionnaire 3, acquired after the experimental task execution, only results of 8 patients out of 10 are available. Missing data are due to physical exhaustion for a patient and the technical failure for another (they did not experience enough for doing this questionnaire). According to the results, 7 patients asserted that they would consider the system as a complement of the therapy and they would use it during the therapy. To the request of considering the device as an assistive system at home and in daily life, only 3 patients out of 8 were positive. Finally, 5 patients out of 8 would like to use

TABLE III
EXPERIMENTAL RESULTS OF THE MODIFIED ACTION RESEARCH ARM TEST (MARAT) AND THE SYSTEM USABILITY SCALE (SUS).

Patient ID	mARAT (30)			SUS (100)		
	Force sensor	Bending sensor	Trigger sensor	Force sensor	Bending sensor	Trigger sensor
1	12	0	25	75	47.5	80
2	1	12	15	60	75	85
3	16	24	27	80	95	97.5
4	⋆	⋆	13	⋆	⋆	32.5
5	14	14	18	75	75	90
6	6	12	17	67.5	72.5	70
7	22	23	29	30	35	87.5
8	◇	6	12	◇	55	85
9	◇	•	3	◇	•	57.5
10	Technical failure					
Median†	13	12	17	75	72.5	85.0
Q1	7.5	9	13	63.8	51.3	70.0
Q3	15.5	18.5	25	77.5	75	87.5

LEGEND

Q1 First quartile;
Q3 Third quartile;
⋆ Dropout for shoulder pain;
◇ Dropout for no finger flexion/extension;
• Dropout for exhaustion;
† Median, Q1 and Q3 values for each input have been calculated with results of those patients who completed the experimental tasks.

the device in combination with a computer game.

Regarding the muscle tone, the mAS scores per muscle and per subject, are reported in Table IV. The first (see Table IV(a)) represents the median value among the 10 patients per muscle, and none of them showed an increase of the tone. The second (see Table IV(b)) is a representative value per each patient, calculated as the mean between the scores of all his/her muscles. Then, the median values among the 10 patients are evaluated: 1.1 (0.9 - 1.6) before the experimental task execution, and 0.9 (0.4 - 1.4) after. No statistically significant differences have been found between them (Wilcoxon rank sum test).

Regarding safety of the system, we already reported 2 dropouts during the experimental sessions: one for shoulder pain, and one for exhaustion.

V. DISCUSSION

In this work, we propose a novel robotic supernumerary hand in combination with an arm gravity support as a compensatory technique to allow chronic stroke patients using their severely affected arm for manipulating objects. The supernumerary hand can be controlled by the patient through three different input interfaces: one of them requires input from the affected limb, while the other two are controlled of the non-affected limb. The system was tested in a single-session test, including ten chronic stroke patients with minimal or no hand function who were not able to manipulate objects. This clinical condition was testified by the inability to perform the experimental tasks without any external support. Whereas, thanks to the proposed system (with all its input interfaces) most of the patients had the chance to manipulate different sized objects. This can be seen in Table III where, except for dropout cases, a score greater than 13/30 was reported by each patient with at least one input interface. Although not a very high score, this result suggests that the proposed system has high potentiality in increasing the residual functionality. This, in turn, could motivate patients for using the impaired limb in coordination with the system and exploit as much as possible the residual abilities. Clearly, further improvements will be necessary, as discussed following, to prevent other dropouts. Examples of tasks, performed with the supernumerary hand system are shown in Figure 6.

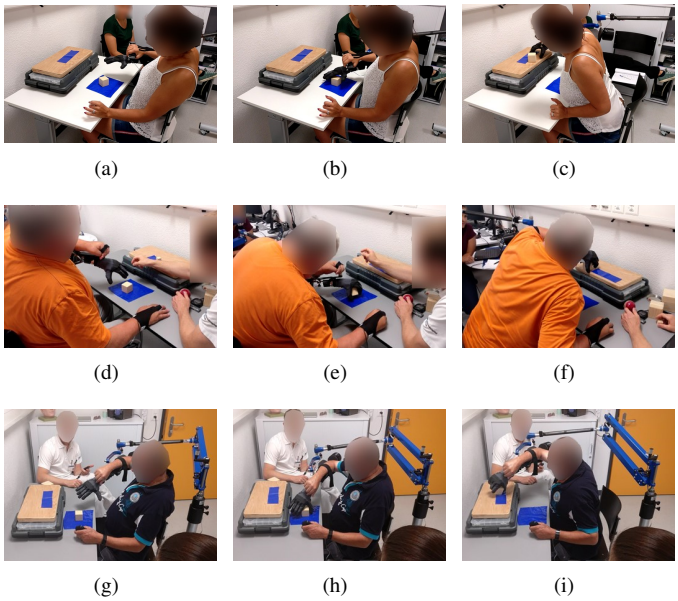

Fig. 6. Pictures show three patients performing tasks during the execution of the modified Action Research Arm Test: (a) to (c), lifting a cube using the grasp force handle input interface; (d) to (f), lifting a cube using the bending sensor; (g) to (i), lifting a cube using the trigger input interface.

Considering the usability assessments, all three input interfaces revealed promising results. Based on the SUS, the patients considered the trigger the best interface, followed by the force sensor and the bending sensor. This could be

explained by the design of each interface. The trigger was the easiest to use, since the patients just needed to push a lever with their non-affected hand. The same was assumed for the bending sensor, but involuntary movement of the finger glove made the use critical. In fact, during the experiment, the sensor misaligned with the finger joints, decreasing the control efficiency of the SoftHand X. The most important feature of the force sensor was that it does not involve the non-affected hand and would thus allow bi-manual activities. Unfortunately, it was also a drawback, because not all the patient could use it, as residual finger movement was required and the control was less accurate. Nevertheless, usability scores for all the three input interfaces were satisfactory in comparison with the literature standards [37], and other devices [19], [38].

An additional option for controlling the system would be using electro-muscular activity (EMG) of the arm/forearm muscles [25], [39], [40]. However, state-of-art EMG patterns recognition approaches are not able to decode movement intention in subjects with neurological injury such as stroke [41]. For this reason, we decided to postpone investigating the use of EMGs as an input method until deeper study. The patients' preference for controlling the system with the non-affected upper limb are in line with the mARAT score, as the highest mARAT score was obtained for manipulating objects with the trigger interface. However, the patients were exposed to the system for a short amount of time and we did not investigate if this would have affected their ability to manipulate objects with the affected limb.

With questionnaires and open comments, an overall appreciation has been reported by the patients, although also improvements were suggested. In particular, they appreciated the load reduction carried out by the gravity compensator and the ease of use of the whole system in general. Most of the comments were related to the design, which resulted a little bulky, e.g. the counter-mass happened to hit several times the gravity support bar during movements. In addition, some patients asserted that they perceived the arm movement as unnatural. Another comment was related to the adaptability of the human-arm interface. Most of the patients asserted that they would need help for using it, reducing his/her autonomy. Concerning the input interfaces, the grasp force handle was unconformable because of its dimension and shape; patients reported that a smaller and more ergonomic handle would be better. Finally, another critical point was the appearance of the SoftHand X. Some patients, in fact, suggested for skin-colored glove, possibly making the robotic hand more realistic, as a real human hand.

In order to monitor the effects on muscle tone due to the use of this novel system, the mAS was measured before and after the experimental protocol. It was shown that the compensational supernumerary hand robotic system does not increase the spasticity, and it may indeed reduce it (although this remains to be statistically demonstrated by a larger study). This is an important outcome for this kind of device, since according to the meta-analysis conducted by Veerbeek et al. in [16], robotic therapy on upper limb often induces an increment of the muscle tone in stroke patients with mild (to moderate) upper limb impairments. However, when using the current system, overloading the shoulder is a risk. This could be explained by the diminished control over the weakened muscles of the proximal part of the arm. Therefore, in the future, shoulder strain should be diminished by the introduction of more sophisticated active gravity compensation solutions (for example by the use of force sensors, motors and proper algorithms capable to estimate force exerted) and closely monitored when using the system.

Although not directly measured within the experimental protocol, additional considerations can be drawn by empirical observations. In particular, the mechanical design of the SoftHand X made it specifically suitable for this kind of system. The joint design, in fact, made the hand robust to accidental impacts, with the fingers adapting to obstacles in the environment. This was quite important, as patients had a reduced arm control, resulting in slamming of the robotic hand against obstacles in the environment during task execution. In addition, the fact that only one motor actuated the SoftHand X, so needing very few control signals (provided by the input interfaces), reduces the need for a training phase for the user (in this work, training was not used at all) and enhanced the intuitiveness of the device. Very helpful was the dual pro-supination mechanical solution of the human-arm interface for helping to approach objects of different size and shape. In particular, the possibility of pre-configuring the SoftHand X pose, in some tasks, through the prosthetic-like wrist was highly used by those patients who had a more impaired range of motion for forearm pronation/supination. Because of the presence of the additional masses (e.g. the robotic hand and the human-arm interface), the Center Of Mass (COM) of the system was too far away from the joint rotational axes. This may induce annoying torques on the patient's arm that may discourage the use of the system. The mass/counter-mass mechanism (described in Sec. II-C) significantly reduces this problem by balancing the device masses and the patient's arm weight. Nevertheless, this weight

TABLE IV
MODIFIED ASHWORTH SCALE (MAS)
ON THE LEFT: MEDIAN VALUES OF THE MAS PER MUSCLE. ON THE RIGHT: MEDIAN VALUES OF MAS PER SUBJECT.
LEGEND: Q1 = FIRST QUARTILE; Q3 = THIRD QUARTILE.

(a)

Muscle	Pre	Post
Pectoralis major	2 (1.5 - 2.8)	1.5 (0.3 - 2)
Biceps	1.5 (1 - 1.5)	0.5 (1 - 2)
Triceps	0.5 (0 - 1.4)	0 (0 - 1)
Wrist extensors	0 (0 - 0.8)	0 (0 - 0)
Wrist flexors	1.75 (1.5 - 2)	1 (1 - 1.5)
Finger extensors	0 (0 - 0)	0 (0 - 1)
Finger flexors	2 (0.3 - 3)	1 (0.3 - 1.9)

Values are median (1^{st} - 3^{rd} quartile).

(b)

Patient ID	mAS pre	mAS post
1	0.9	1.5
2	1.4	0.9
3	0.5	0.1
4	0.9	0.6
5	2.3	1.1
6	1.0	0.9
7	0.1	0.3
8	1.3	0.9
9	2.7	1.9
10	1.7	1.2
Median	1.1	0.9
Q1	0.9	0.6
Q3	1.6	1.2

increment introduces more inertia on the system. Although this was not an evident issue in this study, as the proposed tasks did not request high velocity movements, future work will investigate potential solutions to mitigate these effects. For example, the implementation of active joints could be an interesting solution, since it permits an important reduction of the encumbrance. Alternative systems are represented by soft exoskeletons, which easily could overcome issues like bulkiness and torques balancing thanks to the use of soft materials [42], [43].

Some limitations of this study are related to the experimental protocol. As reported in literature, ten patient should be enough for conducting a usability study [44], but unfortunately, in our work, not all the subjects were able to perform all the experiments. For that reason, it was not possible to statistically compare results between interfaces or relate them to patient characteristics. Nevertheless, important insights have been extracted from the obtained results, as discussed before. A new clinical study is already planned to overcome this issue.

As previously discussed, the trigger and the bending sensor were more preferred as input interfaces. This is not surprising, since controlling the robotic hand with the affected-hand is more difficult due to the motor impairment. Unfortunately, this clearly is a limitation of the proposed system and solutions will be explored in future works. In particular, new input interfaces will be designed with the aim to leave the contralateral hand free. Examples could be a foot control, such as using a pedal [45], or a brain computer interface (BCI) [46]. Improvement for these interfaces will be guided also by the prospect to use the SHX system for in-home assistance. Actually, this hypothesis, in this work, was rejected by the patients, since the system was still not ready for the use in a non-clinical environment. Although most of them declared that they would like to use the system for therapy, mechanical design limits (bulkiness and mass/counter-mass setup) and the need of an expert operator discourage the in-home use. For these reasons, further developments will consider a lighter and more user-friendly design, where the presence of an expert assistant will be not necessary.

Future works will be oriented to the investigation of using this system by patients who have no residual hand function. This will be done by examining also the use of other input interfaces. We believe that not only the use of the residual activities (through input interfaces used by the affected side) can induce some benefits, but also a possible "mirror effect" may lead to positive outcomes [47]. This effect could be enforced by the presence of an anthropomorphic robotic hand close to the affected one, which closes/opens accordingly to the patient's will. Further works will also study compensational strategy adopted by the patient by using this system.

VI. Conclusion

In this work, we presented a novel supernumerary robotic hand system, the SoftHand X, designed for compensating arm-hand functionality in sever post-stroke patients. In particular, we evaluated the usability of the system composed by a gravity compensation system, the HR-MAS, and a soft articulated artificial hand, which can be controlled with three different input interfaces. The key features of the devices made the system robust and suitable for chronic stroke patients with a severe upper limb paresis. In general, we can assert that the supernumerary system allowed patients to perform grasping tasks by using their affected upper limb. To the best of our knowledge, this is the first system providing an arm-hand compensational support to severely affected stroke patients for grasp activities with the paretic side. Contrary to other devices designed for rehabilitation, our system allows compensation of the paretic upper limb by using the affected limb itself. This is important, as it could be an effective strategy to prevent disuse of the paretic limb. In addition, the effects on arm-hand spasticity due to the use of the system were investigated, demonstrating that the system did not induce any increment on the muscle tone. In fact, the proposed system permitted the patients to perform grasping activities by using the residual functionality of the affected arm and hand. Neither a gravity compensator, nor a robotic hand alone could completely compensate severely affected chronic stroke patients' upper limb movements during such grasping tasks.

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Author's contributions

ASC designed the system and drafted the manuscript. MGC supervised the engineering process. ET and JH provided the data of the stroke subjects and assisted with data interpretation. FT and CH designed the gravity support arm. ET, MGC, JH, JV and AA helped to draft the manuscript. AB, MGC, AL and JH supervised the research. All authors read and approved the final manuscript.

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